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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. CONFIRMATION NO | |
|-------------------------|----------------------------|----------------------|-------------------------------------|---------------|
| 10/731,816 | 12/09/2003 | David Burton | 24,577-20US 4416 | |
| 23373 SUGHRUE MI | 7590 01/26/200 ON, PLLC | EXAMINER | | |
| 2100 PENNSY | LVANIA AVENUE, N | TOTH, KAREN E | | |
| SUITE 800 WASHINGTOI | N, DC 20037 | | ART UNIT | PAPER NUMBER |
| | | | 3735 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 01/26/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| Office Action Communication | | Application | on No. | Applicant(s) | | | | |
|---|---|--|---|--|--------------|--|--|--|
| | | 10/731,8 | 16 | BURTON ET AL. | | | | |
| Office Action Summary | | | | Art Unit | | | | |
| | | KAREN E | . ТОТН | 3735 | | | | |
| Period fo | The MAILING DATE of this communication or Reply | appears on the | e cover sheet with the c | orrespondence ac | ldress | | | |
| WHIC - Exter after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR RICHEVER IS LONGER, FROM THE MAILIN nsions of time may be available under the provisions of 37 CF SIX (6) MONTHS from the mailing date of this communicatio period for reply is specified above, the maximum statutory pre to reply within the set or extended period for reply will, by seply received by the Office later than three months after the part of patent term adjustment. See 37 CFR 1.704(b). | G DATE OF THE FR 1.136(a). In no even. eriod will apply and westatute, cause the app | HIS COMMUNICATION ent, however, may a reply be tin III expire SIX (6) MONTHS from lication to become ABANDONE | N. nely filed the mailing date of this of D (35 U.S.C. § 133). | | | | |
| Status | | | | | | | | |
| 1) 又 | Responsive to communication(s) filed on a | 10 October 200 | 8 | | | | | |
| 2a)□ | Responsive to communication(s) filed on <u>10 October 2008</u> . This action is FINAL . 2b)⊠ This action is non-final. | | | | | | | |
| 3) | '— | | | secution as to the | e merits is | | | |
| ٥/ك | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| | closed in absertained with the practice and | doi Ex parto Qu | ay,0, 1000 0. D . 11, 10 | 0.0.2.210. | | | | |
| Dispositi | on of Claims | | | | | | | |
| 4)🛛 | Claim(s) <u>56-58,61-67,69-73 and 78-80</u> is/a | are pending in t | he application. | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5)🖂 | | | | | | | | |
| | ✓ Claim(s) 62, 66, 79 is/are rejected. | | | | | | | |
| · · | Claim(s) is/are objected to. | | | | | | | |
| - | · · | nd/or election r | equirement | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | | |
| Applicati | on Papers | | | | | | | |
| 9) | The specification is objected to by the Exar | miner. | | | | | | |
| 10) | The drawing(s) filed on is/are: a) | accepted or b) | objected to by the I | Examiner. | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | |
| | | = | | | FR 1.121(d). | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | |
| | • | | | | | | | |
| Priority ι | ınder 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| 2) Notice (3) Inform | t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948 mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date | 3) | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate | | | | |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. Claims 66 and 79 are rejected under 35 U.S.C. 103(a) as being anticipated by Chamoun (US Patent 5320109) in view of Vierto-Oja (US 2002/0173729).

Chamoun discloses a method comprising acquiring a first continuous biosignal with an electrode sensor that is activatable in response to pressure (column 3, lines 30-32), stimulating an evoked potential response signal and deriving an evoked potential response signal from the first biosignal (column 11, lines 35-44), deriving a first index of consciousness from the first biosignal and a second index of consciousness from the evoked potential signal (column 5, lines 22-27; column 10, lines 41-50), and using the indices to determine the patient's consciousness level (column 4, lines 3-18, column 7, lines 51-62; column 18, lines 58-64). The Examiner notes that, though Chamoun does not explicitly disclose the electrodes as being activated by pressure, the limitation is merely a citation of intended use, and Chamoun's electrodes are certainly capable of being activated in response to pressure. Though Chamoun discloses monitoring the patient's consciousness level, Chamoun does not specifically disclose determining when the patient enters and leaves consciousness.

Vierto-Oja teaches a method of monitoring a patient's state by using electrode signal data to determine indices that can be used to find when a patient enters and

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leaves consciousness (paragraphs [0037], [0039], [0043], [0054]), in order to effectively monitor the patient's condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Chamoun and used the indices to determine when the patient enters and leaves consciousness, as taught by Vierto-Oja, in order to effectively monitor the patient's condition.

3. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chamoun in view of Vierto-Oja, as applied above, and further in view of Ennen (US Patent 621627).

Chamoun discloses all the elements of the claimed invention, as described above, except for monitoring the signals for signal quality. Ennen teaches obtaining biosignals from a patient, where the signals are regularly monitored for signal quality (column 3 line 63 to column 4 line 2; column 4, lines 20-24 and 59-61), in order to ensure the accuracy of the signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Chamoun and monitored signal quality, as taught by Ennen, in order to ensure the accuracy of the captured data.

Allowable Subject Matter

4. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to anticipate or make obvious the methods of claims 56-58, 61, 63-65, 67, 69-73, 78, and 80, including, *inter-alia*, acquiring a first continuous

biosignal, stimulating an evoked potential response signal, deriving an evoked potential response signal from the first biosignal, deriving a first index of consciousness from the first biosignal, deriving a second index of consciousness from the evoked potential signal, and using the indices in a weighting process to determine whether a monitored being is entering or leaving consciousness based on the indices.

Chamoun discloses a similar method, except for using a weighting process on the indices to classify the being's state of consciousness.

Response to Arguments

5. Applicant's arguments filed 10 October 2008 have been fully considered but they are not persuasive.

Applicant has argued that Chamoun's electrodes are not activatable in response to pressure. The Examiner notes that this limitation is merely a recitation of intended use. Chamoun's electrodes are certainly capable of being activated in response to pressure from a user.

The remainder of the arguments directed to Chamoun are moot in view of the new grounds of rejection.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/ Primary Examiner, Art Unit 3735

/K. E. T./ Examiner, Art Unit 3735